

## **REMARKS**

Claims 58-74 are currently pending in this application. In the Office Action mailed on August 21, 2007 ("Office Action"), claims 58-74 were rejected. Through this amendment, Applicants have amended claim 58. No new matter has been entered. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

### **I. Claim Rejections– 35 USC 102(b) - Allen**

Claims 58, 59, 62-65 and 67 were rejected under 35 USC 102(b) as being anticipated by US Patent No. 5,733,288 to Allen. Applicants respectfully traverse this rejection as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C. 102(b), it must be shown that each and every element of the claim can be found in the reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 58, as amended, describes a method for removing intervertebral disc material. The first step involves creating a working channel from a patient's skin to an intervertebral disc space. The second step involves inserting a brush member into said intervertebral disc space, wherein the brush member has a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. The next step involves manipulating the brush member within the intervertebral disc space to receive intervertebral disc material within the brush member. The last step involves removing the brush member from the intervertebral disc space.

The Allen reference appears to be silent with regard to at least one element found in claim 58, such that the rejection for anticipation should be withdrawn. The Allen reference does not disclose the element of claim 58 of the present invention that involves a “brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material.” Although the Allen reference may disclose a bone brush, the Allen reference does not disclose the specific dimensions for length and diameter of Applicant’s brush member. Further, the bristle members (referred to as brush fibers) of Allen’s bone brush are not disposed in a helical configuration, as in Applicant’s invention.

The brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material is essential to Applicant’s claim for many reasons. First of all, the dimensions of Applicant’s brush member are precisely designed for manipulation within an intervertebral disc space. Thus, when used for removing intervertebral disc material, the brush member having a length ranging from 0.25 to 4.0 inches and a diameter ranging from 0.082 to 1.225 inches is perfectly adapted to that exact region of the spine. Applicant’s invention is a specialized brush member that is configured for the particular use of removing intervertebral disc material inside an intervertebral disc space. Having those specified dimensions, the brush member is basically custom-made or suited for a surgical procedure in the intervertebral disc space.

Secondly, the helical configuration of the bristle members is important because it provides an optimal capacity for carrying intervertebral disc material. Since the brush member defines the capacity to remove, collect, and carry the intervertebral disc material, the arrangement of the bristle members is crucial to the performance of that function. In Applicant’s brush member, having the bristle members disposed in a helical configuration creates a highly effective and efficient way of removing, collecting, and carrying body tissue. A helical arrangement of the

bristle members equips the brush member with two capacities for collecting and carrying body tissue: 1) the space between the individual bristle members themselves, and 2) the helical space between the groupings of bristle members in relation to their helical configuration. With a helical configuration, the helical space between the groupings of bristle members provides a larger capacity for carrying disc material. While containing the disc material between the helical groupings of bristle members (as well as in between the individual bristle members themselves), the helical configuration allows for large amounts of tissue to be removed. As a result, the time required for the removal of body tissue is reduced. In this manner, Applicant's brush member with a helical configuration of bristle members offers a more efficient approach for carrying and removing intervertebral disc material.

By contrast, the Allen reference does not include a brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. The Allen reference does have a brush member, however, it does not have the specified dimensions or helical configuration of Applicant's claim. Instead, Allen's brush member (referred to as a round brush fiber head) has bristle members that are woven around a locking ring (column 2, lines 63-65). In addition, the bristle members simply extend outward to form a circular shape (column 3, lines 63-66). As such, the brush of the Allen reference does not have the larger capacity for carrying disc material that is accounted for with the helical configuration in Applicant's claim. To the contrary, the Allen reference does not even take into consideration the efficiency that could be gained from providing a space between groupings of bristle members, as found in Applicant's invention. The Allen reference also does not provide a length range or diameter range for the brush member that would assist in conforming it to an intervertebral disc space. As such, the Allen brush is not specially made for an intervertebral disc space, unlike the Applicant's brush member which is dimensioned for use in an intervertebral disc space.

Because Allen fails to teach or disclose at least one claimed feature in the independent

claim 58, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited. Since rejected claims 59, 62-65 and 67 are all dependent upon independent claim 58, it follows that Applicants believe these claims to be in condition for allowance, and respectfully request a favorable indication in that regard.

## **II. Claim Rejections - 35 USC 103(a)**

### **A. Allen in view of Ouchi**

Claims 60, 61, 68 and 69 were rejected under 35 USC 103(a) as being unpatentable over Allen in view of US Patent No. 5,899,850 to Ouchi. Applicants respectfully traverse this rejection as set forth below.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

As noted above, Allen failed to teach or disclose at least one feature found in independent claim 58. More specifically, Allen does not appear to teach or contemplate a brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches,

and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material.

The Ouchi reference does not cure the aforementioned deficiencies in what was fairly taught by Allen. The Ouchi reference may disclose a brush member having bristles that are arranged in a spiral (column 6, lines 3-5). However, the Ouchi reference does not disclose a brush member having a length ranging from 0.25 to 4.0 inches and a diameter ranging from 0.082 to 1.225 inches. As opposed to Applicant's brush which is adapted for use within an intervertebral disc space, the Ouchi reference discloses a cytology brush that is a "treatment accessory for an endoscope" (column 1, lines 57-60). Ouchi's brush member was not designed for removing intervertebral disc material. Ouchi's brush member was dimensioned for use inside an endoscope. As such, it does not appear that Ouchi's cytology brush is capable of clearing all the intervertebral disc material within a disc space. The specified dimensions of Applicant's claim that make the brush member suitable for intervertebral disc removal can not be applied to Ouchi's cytology brush because a cytology brush having those specified dimensions would not appear to fit inside an endoscope, or be appropriate to use within an endoscope. Unlike Applicant's brush member, which is specialized for use within an intervertebral disc space, the Ouchi reference only discloses a brush member for use in endoscopy.

Therefore, given this void, one of ordinary skill in the art would not have been motivated to combine the Allen and Ouchi references, nor would such a combination have led them to arrive at the present invention as claimed. Based on the foregoing, Applicants respectfully submit that the Allen and Ouchi references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention. Claims 60, 61, 68 and 69, being dependent upon and further limiting claim 58, should be allowed for the reasons set forth above in support of the allowability of claim 58, as well as the additional features it contains. Applicants respectfully request that the rejection of claims 60, 61, 68 and 69 be withdrawn in favor of an indication of allowance, which is hereby

earnestly solicited.

**B. Allen in view of Ouchi in view of Ouchi**

Claims 70-74 were rejected under 35 USC 103(a) as being unpatentable over Allen in view of Ouchi (US Patent No. 5,899, 850, “first Ouchi reference”) in view of Ouchi (US Patent No. 6,210,377 B1, “second Ouchi reference”). Applicants respectfully traverse this rejection in light of the amendments to the claims and as set forth below.

In order for combined references to anticipate the present claimed invention under 35 U.S.C. 103(a), the references must teach or suggest all of the claim limitations when combined. If it can be shown that one element of the claim is missing or not met by the cited references, the rejection must be withdrawn as inappropriate.

As noted above, both the Allen reference and the first Ouchi reference failed to teach or disclose at least one feature found in independent claim 58. More specifically, neither the Allen reference nor the first Ouchi reference teach or contemplate a brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. The second Ouchi reference does not cure the aforementioned deficiencies in what was fairly taught by the Allen reference and the first Ouchi reference.

That is, the second Ouchi reference also does not appear to teach or contemplate a brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. In fact, the second Ouchi reference does not even teach a brush member. The second Ouchi reference teaches an injector instrument, or another treatment accessory for an endoscope that is used for injecting a medical fluid into tissue within a body cavity (column 1, lines 9-12). The only mention of a brush instrument is for modifying a

packing in case a cytology brush instrument is used (column 29, lines 11-21). Given this void, one of ordinary skill in the art would not have been motivated to combine the Allen reference, the first Ouchi reference, and the second Ouchi reference, nor would such a combination have led them to arrive at the present invention as claimed.

Claims 70-74 being dependent upon and further limiting independent claim 58 should be allowed for the reasons set forth above in support of the allowability of claim 58, as well as the additional features it contains. Applicants respectfully request that the rejection of claims 70-74 be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

#### **C. Allen in view of Worthen**

Claim 66 was rejected under 35 USC 103(a) as being unpatentable over Allen in view of US Patent No. 5,445,164 to Worthen et al ("Worthen"). Applicant respectfully traverses this rejection in light of the amendments to the claims and as set forth below.

As noted above, Allen failed to teach or disclose at least one feature found in independent claim 58. More specifically, Allen does not appear to teach or contemplate a brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. The Worthen reference does not cure the aforementioned deficiencies in what was fairly taught by Allen.

Although the Worthen reference discloses a circular brush (column 2, lines 54-58), the Worthen reference does not teach or contemplate a brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. The Worthen reference discloses an initially straight brush that is subsequently deformed into a generally circular configuration (column 2, lines 63-66). Thus, Worthen's brush

is not in the helical configuration of Applicant's brush. Furthermore, Worthen's circular brush has a diameter of about 3.5 centimeters (column 3, lines 3-6). That disclosed diameter (3.5 centimeters = 1.38 inches) is outside the diameter range of Applicant's brush because the Worthen brush is used for collecting tissue in a woman's cervix, not removing intervertebral disc material. Thus, the Worthen reference does not disclose a brush member having the specific elements of Applicant's invention, making it a brush specialized for use within an intervertebral disc space. Given this void, one of ordinary skill in the art would not have been motivated to combine the Allen and Worthen references, nor would such a combination have led them to arrive at the present invention as claimed.

Claim 66, being dependent on independent claim 58, should be allowed for the reasons set forth above in support of allowability of claim 58, as well as the additional features it contains. Applicant respectfully requests that the rejection of claim 66 be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.




## CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,  
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